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The new vision from the National Institute of Allergy and Infectious Diseases (NIAID)

Jeffery K. Taubenberger, John H. Powers & Jay Bhattacharya

Preparing for tomorrow's threats by enhancing our ability to help patients today.

For decades, National Institute of Allergy and Infectious Disease (NIAID) research has focused on three areas: HIV, biodefense/pandemic preparedness, and all other immunological and infectious diseases combined. NIAID's new vision will refocus on the two related pillars of infectious diseases and immunology, opening wider areas for research into the challenges most relevant to keeping Americans healthy today.

During the COVID-19 pandemic, the NIAID and its then-director, Anthony Fauci, became, for many, the face of the pandemic response[1]. Although not directly under NIAID's purview, many of the recommended policies, including lockdowns, social distancing, school closures, wearing masks and vaccine mandates, lacked robust confirmatory evidence and remain the subject of debate about their overall benefits and unintended consequences[2]. Where enforced, vaccine mandates contributed to decreased public confidence in routine voluntary immunizations[3]. We recognize that much of the American public lost trust in the NIAID, the National Institutes of Health (NIH; of which the NIAID is a part), and in the greater scientific community[4].

As current leaders of the NIH and the NIAID, we acknowledge this breach of trust, but we remain committed to the idea that the scientific method used to generate valid, clinically relevant evidence can and must be applied to the continuing challenges of allergic, immunological and infectious diseases. These remain as important as ever to making America healthy. NIAID's role is to develop and disseminate evidence by performing and funding meritorious research to address important biomedical questions, not in setting policy.

Over the past quarter of a century, NIAID's overall strategic plan — which is being updated after almost a decade — had three main foci: (1) HIV research, including developing a vaccine or cure; (2) civilian biodefense and pandemic preparedness; and (3) all other priorities, including most infections and allergic, immunological and autoimmune conditions. To this end, we articulate here a new vision for the work of the NIAID in the twenty-first century. As infectious agents and immune responses and our understanding of them evolve, the research agenda should evolve to address their crucial roles in maintaining human health and preventing or treating disease.

NIAID can point to considerable success in HIV research[5]. There are now safe, effective and more convenient medications to prevent and treat HIV infection, thanks to NIAID-funded research, as well as numerous advances in basic science that have resulted in improved health. Yet HIV persists as an ongoing threat to Americans, with nearly 40,000 individuals newly infected annually[6]. On pandemic preparedness, regardless of one's position on the origin of SARS-CoV-2, NIAID's work clearly neither prevented the pandemic nor prevented Americans from experiencing among the highest levels of all-cause excess mortality in the developed world during that time[7]. Finally, given the increasing prevalence of allergic and autoimmune disorders and the burden of common infections in the population over the past few decades[8], the NIAID must focus research on these conditions with a greater sense of urgency.

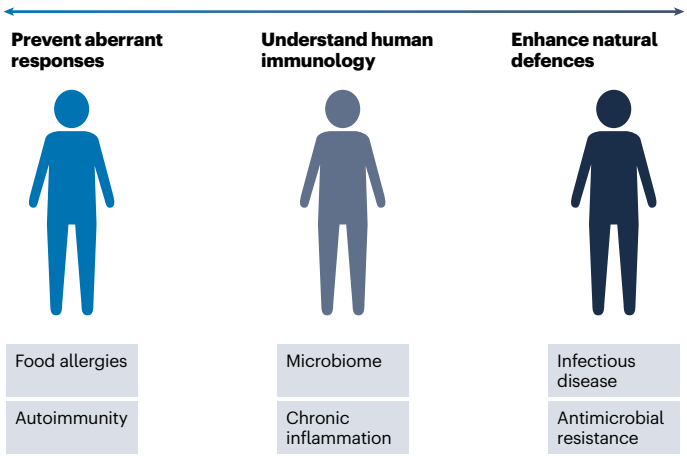

Fig. 1 | The NIAID strategic vision. An integrated, holistic approach to immunological and infectious disease research to improve human health.

Given these considerations, our vision for reforming the NIAID is to replace these three strategic aims with just two: (1) to address the most impactful infectious diseases that Americans currently face with evidence from gold standard science; and (2) to support innovative research to address fundamental studies in immunology and allergic and autoimmune diseases to improve patient outcomes (Fig. 1).

Strategic aim 1: support research to address important challenges in infectious diseases that affect Americans

A key part of NIAID's portfolio will be to achieve progress in the aspirational goal first articulated by President Trump in his 2019 State of the Union speech: ending the HIV epidemic in the USA by the end of this decade. In the past year, key technological breakthroughs for the long-term prevention of HIV infection[9], owing largely to NIAID-funded research, provided tools to make progress towards accomplishing this aim. We should celebrate these tremendous achievements while we learn how best to apply those successes in real-world settings. Collaborating with other NIH institutes and partners[10], we will expand research on how to implement tools to control HIV in the USA. Concurrently, we will maintain a strong research and development pipeline for additional long-acting antiviral agents and other new therapeutic and preventative strategies to complement this crucial implementation research.

The second part of the NIAID portfolio will be improving patient outcomes in both acute and chronic infections, irrespective of the type of microorganism causing the disease. These infectious illnesses, in

addition to HIV, substantially affect the health of Americans. Although we cannot accurately predict future pandemics or new infectious disease outbreaks, we can and must prepare for future events by renewing our focus on improving patient outcomes with common infections. These include disease from seasonal influenza viruses, arthropod-borne diseases, and common bacterial, viral, fungal and parasitic infections, that collectively kill or cause morbidity in tens of thousands of Americans annually. These cause the greatest burdens of disease in patients today. We can best serve Americans, for example, by improving on the suboptimal effectiveness of current influenza vaccine strategies.

We will place renewed emphasis on research in patients who experience antimicrobial resistance, by defining antimicrobial resistance as patients who have poor outcomes on current therapies, rather than solely on the in vitro biological activity of drugs against specific organisms[11]. NIH research shows that 94% of deaths and over 99% of serious infections are associated with organisms that are 'susceptible' in vitro to currently available therapies. However, these patients still experience poor outcomes as their disease is 'resistant' in vivo to the effects of current drugs[12] owing to host factors and the need for better rapid point-of-care diagnosis.

Focusing on patients who lack current effective therapies will open new areas of research on phage-, microbiome- and host-directed therapies with the goal of improving overall patient outcomes. The overuse and misuse of antibiotics in humans and animals, underperforming diagnostics, and hospital-acquired infections still impact patients' lives. The NIAID will continue to focus on basic and clinical research to address these serious problems.

Third, the NIAID will strictly adhere to new regulatory frameworks on dangerous gain-of-function research, as defined in President Trump's Executive Order 14292 in May 2025, and which will be established by the Office of Science and Technology Policy. We will ensure that NIH-supported research follows the new guidelines, review processes and prohibitions. Although most infectious disease research poses no catastrophic threat to human populations, those projects that do will have no part in the NIAID portfolio going forward.

Strategic aim 2: support research addressing key problems in immunology and allergic and autoimmune disorders affecting Americans

A better understanding of immune system development and homeostasis is the key to unlocking solutions for health, and many diseases that Americans face. The NIAID must support basic, applied and clinical immunology research to address the ever-increasing chronic diseases that affect Americans. These include not only the short- and long-term effects of infections, allergies and autoimmunity, but also the immunopathology that underlies common chronic diseases such as heart disease and diabetes.

The NIAID will foster research to better understand long-term post-infectious and non-infectious inflammatory syndromes, such as long COVID, chronic Lyme disease, myalgic encephalitis/chronic fatigue syndrome, and adverse events after vaccination. This work will also extend to advancing scientific evidence on possible infectious triggers or contributors to other chronic diseases, such as type 1 diabetes mellitus and multiple sclerosis. Such research supporting immunology and collaboration across institutes will dramatically improve our scientific understanding of all chronic diseases.

The NIAID will expand work to identify the causes of allergic and autoimmune diseases, beginning in childhood and throughout life, focusing on prevention. Although we continue research on the treatment and management of these diseases, this new focus will identify ways to reduce the risk of their development and prevalence. This will also require further research to understand the crucial role of the human microbiome in the development and maintenance of the immune system and the consequences of microbiome alteration in health and disease[13]. A better understanding of the complexities of immune responses[14] will also be needed to develop a new generation of safer and more effective therapeutics and vaccines[15].

Ultimately, with these changes to the NIAID's strategic aims, we will refocus the institute's important research on areas that currently affect the American people. These priorities, in addition to the important ongoing and funded research portfolio, will collectively better prepare us for the future by driving basic, translational and clinical research that addresses the health challenges in immunological and infectious diseases that Americans face today.

Jeffery K. Taubenberger [1] ✉, **John H. Powers** [2] & **Jay Bhattacharya** [3]

[1]Office of the Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, MD, USA. [2]Frederick National Laboratory for Cancer Research, Clinical Research Directorate, Frederick, MD, USA. [3]Office of the Director, National Institutes of Health, Bethesda, MD, USA.
✉e-mail: taubenbergerj@niaid.nih.gov

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Competing interests

The authors declare no competing interests.